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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/648,092	06/21/1996	JOHNSTON W. MCAVOY	UNSYD-39709	8661
24201	7590	12/19/2005	EXAMINER	
FULWIDER PATTON 6060 CENTER DRIVE 10TH FLOOR LOS ANGELES, CA 90045			FAY, ZOHREH A	
			ART UNIT	PAPER NUMBER
			1618	
DATE MAILED: 12/19/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/648,092	Applicant(s) MCAVOY ET AL.	
	Examiner Zohreh A. Fay	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-28 and 39-44 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 14-28 and 39-44 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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Claims 14-28 and 39-41 are presented for examination.

The amendments and remarks filed on September 23, 2005 have been received and entered.

Claims 14-28 and 39-41 are again rejected under 35 U.S.C. 112 first paragraph for the reasons set forth on page 2-4 of the office action of January 26, 2005.

Claims 19-23 are rejected under 35 U.S.C. 102 (b) as being anticipated by WO 92/17206 for the reasons set forth on page 4 of the office action of January 26, 2005.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-28 and 39-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The following precedent is believed relevant to the instant case. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), cert. Denied, 523 U.S. 1089 S.Ct. 1548 (1998), hold that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." *Eli Lilly*, 119, F.3d at 1566. The Federal Circuit Court has adopted the standard set forth in the Patent and Trademark Office guidelines for examination of Patent applications under 35 U.S.C. 112 first "written

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Description" requirement ("Guidelines"), 66 Fed.Reg 1099 (Jan. 5, 2001), which state that a written description can be met by "showing that an invention is complete by disclosure of sufficient detailed, relevant identifying characteristics, "including, inter alia, functional characteristics when coupled with a known or disclosed correlation between function and structure...."Enzo Biochem, inc. v. Gen-Probe inc., 296 F.3d, 316 1324-25 (Fed. Cir. 2002) (quoting guideline, 66 Fed Reg. At 1106 (emphasis added)). Moreover, although Eli Lilly and Enzo were decided within the factual content of DNA sequences, this does not preclude extending those reasoning of those cases to chemical structures in general. Univ. of Rochester v.G.D. Searle 7 Co., 249 F. supp. 2d 216, 225 (W.D.N.Y.2003).

Applying the reasoning of the above-cited case law to the facts at hand, the instant specification fails to provide an adequate written description of suitable inhibitors of TGFB. The specification describes only a limited number of inhibitors of TGFB. The instant claims generally recite "one or more inhibitors of TGFB". When functional claims are drawn this broadly, they are inclusive of any TGFB inhibitors, which can be small molecules, peptides, peptide mimetics or RNA-DNA based structure. The instant specification, quite simply, cannot provide direction for using any peptides, proteins or RNA-DNA based structures, in the absence of any identifying characteristics of any kind, e.g. sequences. Accordingly, the instant specification fails to provide an adequate written description of 'one or more inhibitors of TGFB" generally.

Applicant's arguments regarding the 112 rejection have been carefully considered, but are not deemed to be persuasive. Applicant fails to provide information

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allowing skilled artisan to ascertain the compounds without undue experimentation. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all "inhibitors of TGFB", necessitating an exhaustive search for the embodiment suitable to practice the claimed invention. Applicant's arguments and remarks regarding the 102 (b) rejection have also been carefully considered, but are not deemed to be persuasive. The intended use for an old composition does not create a patentably distinct composition. To use an old composition for ophthalmic application does not render the composition new in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh A. Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Z.F

